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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,414	05/11/2005	Kouhei Toyooka	074129-0521	7101
22428	7590	09/26/2007		
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER JARRELL, NOBLE E	
			ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			09/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,414	<b>Applicant(s)</b> TOYOOKA ET AL.	
	<b>Examiner</b> Noble Jarrell	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Claims 1-16 are pending in the current application. This is a National Stage of PCT/JP03/14986, filed 11/2/2003, which claims priority to JP 2002-342399, filed 11/26/2002.

### *Election/Restrictions*

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 10-15, drawn to compounds, compositions, and a method of formula (I) where variable A is piperazine.

Group II, claim(s) 1-6, 13-15, drawn to compounds, compositions, and a method of formula (I) where variable A is azepane (also known as homopiperidine).

Group III, claim(s) 1-6, 13-15, drawn to compounds, compositions, and a method of formula (I) where variable A is piperidine.

Group IV, claim(s) 1-6, 13-15, drawn to compounds, compositions, and a method of formula (I) where variable A is 2-dimethylaminoethylamino.

Group V, claim(s) 1-6, 13-15, drawn to drawn to compounds, compositions, and a method of formula (I) where variable A is 2-thiazolylamino.

Group VI, claim(s) 1-6, 8, 10, 13-15, drawn to compounds, compositions, and a method of formula (I) where variable E is H or alkyl.

Group VII, claim(s) 1-6, 13-15, drawn to compounds, compositions, and a method of formula (I) where variable E is 2-dimethylaminoethylamino.

Group VIII, claim(s) 1-6, 13-15, drawn to compounds, compositions, and a method of formula (I) where variable E is pyridine.

Group IX, claim(s) 1-6, 13-15, drawn to compounds, compositions, and a method of formula (I) where variable E is tetrahydro-2H-pyran.

Group X, claim(s) 1-6, 13-15, drawn to compounds, compositions, and a method of formula (I) where variable E is piperidine.

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Group XI, claim(s) 1-6,13-15, drawn to compounds, compositions, and a method of formula (I) where variable E is cyclopentane or cyclohexane.

Group XII, claim(s) 1-6,13-15, drawn to compounds, compositions, and a method of formula (I) where variable E is cyclohexylmethyl.

Group XIII, claim(s) 1-6,13-15, drawn to compounds, compositions, and a method of formula (I) where variable E is phenyl.

Group XIV, claim(s) 1-6, 9-10, 13-15, drawn to compounds, compositions, and a method of formula (I) where variable L is  $(\text{CH}_2)_n\text{-H}$ .

Group XV, claim(s) 1-7,13-15, drawn to compounds, compositions, and a method of formula (I) where variable A is alkyl.

Group XVI, claim(s) 1-7, 13-15, drawn to compounds, compositions, and a method of formula (I) where variable T is O and G is alkylcarbonyl.

Group XVII, claim(s) 1-6, 9-10, 13-15, drawn to compounds, compositions, and a method of formula (I) where variables T and G are oxygen and alkyl, respectively.

Group XVIII, claim(s) 1-6,13-15, drawn to compounds, compositions, and a method of formula (I) not covered by groups I-XVII.

Group XIX, claim(s) 1-7,10-15, drawn to compounds, compositions, and a method of formula (I) where variable A is piperazine.

Group XX, claim(s) 1-6,13-14,16, drawn to compounds, compositions, and a method of formula (I) where variable A is azepane (also known as homopiperidine).

Group XXI, claim(s) 1-6,13-14,16, drawn to compounds, compositions, and a method of formula (I) where variable A is piperidine.

Group XXII, claim(s) 1-6,13-14,16, drawn to compounds, compositions, and a method of formula (I) where variable A is 2-dimethylaminoethylamino.

Group XXIII, claim(s) 1-6,13-14,16, drawn to drawn to compounds, compositions, and a method of formula (I) where variable A is 2-thiazolylamino.

Group XXIV, claim(s) 1-6, 8, 10,13-14,16, drawn to compounds, compositions, and a method of formula (I) where variable E is H or alkyl.

Group XXV, claim(s) 1-6,13-14,16, drawn to compounds, compositions, and a method of formula (I) where variable E is 2-dimethylaminoethylamino.

Group XXVI, claim(s) 1-6,13-14,16, drawn to compounds, compositions, and a method of formula (I) where variable E is pyridine.

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Group XXVII, claim(s) 1-6, 13-14, 16, drawn to compounds, compositions, and a method of formula (I) where variable E is tetrahydro-2H-pyran.

Group XXVIII, claim(s) 1-6, 13-14, 16, drawn to compounds, compositions, and a method of formula (I) where variable E is piperidine.

Group XXIX, claim(s) 1-6, 13-14, 16, drawn to compounds, compositions, and a method of formula (I) where variable E is cyclopentane or cyclohexane.

Group XXX, claim(s) 1-6, 13-14, 16, drawn to compounds, compositions, and a method of formula (I) where variable E is cyclohexylmethyl.

Group XXXI, claim(s) 1-6, 13-14, 16, drawn to compounds, compositions, and a method of formula (I) where variable E is phenyl.

Group XXXII, claim(s) 1-6, 9-10, 13-14, 16, drawn to compounds, compositions, and a method of formula (I) where variable L is  $(CH_2)_n-H$ .

Group XXXIII, claim(s) 1-7, 13-14, 16, drawn to compounds, compositions, and a method of formula (I) where variable A is alkyl.

Group XXXIV, claim(s) 1-7, 13-14, 16, drawn to compounds, compositions, and a method of formula (I) where variable T is O and G is alkylcarbonyl.

Group XXXV, claim(s) 1-6, 9-10, 13-14, 16, drawn to compounds, compositions, and a method of formula (I) where variables T and G are oxygen and alkyl, respectively.

Group XXXVI, claim(s) 1-6, 13-14, 16, drawn to compounds, compositions, and a method of formula (I) not covered by groups XIX-XXXV.

The inventions listed as Groups I-XXXVI do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(f) "Markush practice" The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

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(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

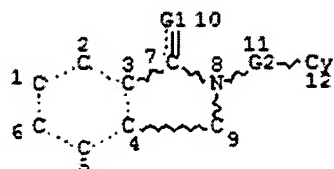
In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The different variables  $R^1$ ,  $R^2$ , and L result in compounds that achieve a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus. Thus lack of unity is apparent.

A preliminary search of a selected core gave numerous iterations, see below:

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=&gt; d que sta

L1 STR



VAR G1=O/S

REP G2=(0-1) AK

NODE ATTRIBUTES:

DEFAULT MLEVEL IS ATOM

DEFAULT ELEVEL IS LIMITED

GRAPH ATTRIBUTES:

RING(S) ARE ISOLATED OR EMBEDDED

NUMBER OF NODES IS 12

STEREO ATTRIBUTES: NONE

L2 50 SEA FILE=REGISTRY SSS SAM L1

8.2% PROCESSED 2000 ITERATIONS

50 ANSWERS

INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE \*\*COMPLETE\*\*

BATCH \*\*COMPLETE\*\*

PROJECTED ITERATIONS: 477464 TO 496136

PROJECTED ANSWERS: 113681 TO 122903

Thus it is clear that applicant's compound core is not applicant's contribution over the prior art and the commonly shared structure does not constitute a structurally distinctive portion in view of the existing prior art. Thus there is a lack of unity.

A prior art reference anticipating the claims with respect to one group would not render obvious the same claims with respect to another group. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention.

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3. Inventions I-XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different structural cores and different methods of use. Inventions I-XVIII and XIX-XXXVI are drawn to different methods of use, manufacturing a pharmaceutical composition for use as a sedative and inducing a sedative effect in a mammal. Inventions I-XVIII and XIX-XXXVI are patentably distinct because each group has a patentably distinct chemical moiety for variable L. The portion of the molecule that is not variable (isoindolin-1-one or isoindolin-1-thione) does not represent a major core of what can be present when variable R<sup>1</sup>, R<sup>2</sup>, and L each have groups. For example, if variable L has a piperidine or piperazine ring, that ring takes priority over the indoline ring. Thus, groups I-XXXVI are unrelated.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species groups I-XXXVI and compounds of claims 10-11. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 4 are generic.



There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the

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election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

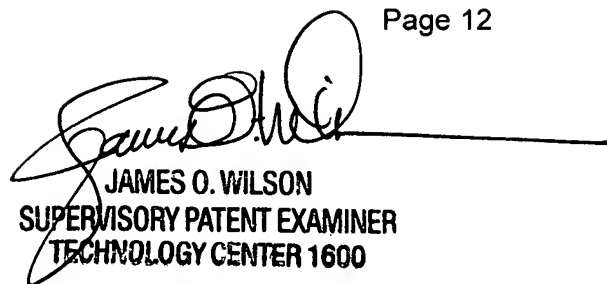
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Noble Jarrell /NJ/

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**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**